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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/665,522	09/22/2003	Andre Stamm	31672-224622	5813

26694 7590 06/07/2011

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EXAMINER	
AHMED, HASAN SYED	

ART UNIT	PAPER NUMBER
1615	

MAIL DATE	DELIVERY MODE
06/07/2011	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)
	10/665,522	STAMM ET AL.
	Examiner	Art Unit
	HASAN AHMED	1615

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *21 March 2011*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *6,7,13,14,16,18-20,25-33,36,38,39 and 41-44* is/are pending in the application.

4a) Of the above claim(s) *6,7,13,14,25-33,38,39 and 46-48* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *16, 18-20, 36 and 41-45* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Receipt is acknowledged of applicants' remarks, filed on 21 March 2011. Applicants' remarks with respect to the Ghebre-Sellassie reference are persuasive, as such, said rejection is hereby withdrawn.

* * * * *

Claim Objections

Claims 6, 7, 13, and 14 are objected to because of the following informalities: the claims depend from cancelled claims. Appropriate correction is required.

* * * * *

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 16, 18-20, 36 and 41-45 remain rejected under 35 U.S.C. 103(a) as being unpatentable over Krause (U.S. Pat. No. 4,859,703) in view of Deboeck et al. (hereinafter "Deboeck") (U.S. Pat. No. 5, 545,628).

Krause ('703) teaches single dose formulations containing a combination of a lipid regulating agent selected from gemfibrozil, clofibrate, bezafibrate or fenofibrate and an ACAT inhibiting agent that are effective pharmaceutical formulations for regulating

blood serum lipid and cholesterol levels (see Abstract); (col. 2, lines 12-22); (col. 4, lines 15-19).

Oral administration forms taught include tablets, as well as capsules, powders and sachets (col. 5, lines 12-20). Powders and tablets contain between about 5 to about 70% by weight of the active ingredient.

The pharmaceutical preparations can be in unit dosage forms (col. 5, lines 36-44).

In therapeutic use, as hypolipidemic or hypcholesterolemic agents, the pharmaceutical compositions are administered to the patient at dosage levels of from 300 to 1200 mg per day of the lipid regulating agent, which can be selected from among others, fenofibrate (col. 5, lines 45-58).

Examples 5-10 at columns 7-9 demonstrate various immediate release tablet formulations comprising a lipid regulating agent selected from gemfibrozil, clofibrate, bezafibrate and fenofibrate. Example 5, for instance presents an immediate release tablet formulation containing 300 mg of lipid regulating agent chosen from gemfibrozil, clofibrate, bezafibrate and fenofibrate. Similarly, Example 6 demonstrates an immediate release tablet formulation containing 450 mg of lipid regulating agent.

Krause teaches that the pharmaceutical compositions are administered at dosage levels of from 300 to 1200 mg per day of the lipid regulating agent, such as for instance, fenofibrate (col. 5, lines 45-58).

Krause does not teach fenofibrate to be provided in a daily dose lower than 200 rag.

Deboeck et al. ('628) teach a pharmaceutical composition provided for treating hyperlipidemia or hypercholesterolemia or both, which contains an effective amount of fenofibrate and an excipient (see Abstract); (col. 1, line 6 - col. 2, line 67).

Deboeck teaches that generally, the effective daily amount of fenofibrate for humans ranges from about 100 mg to 600 mg per day, and preferably from about 100 to 300 mg per day (col. 8, lines 18-24); and Claim 12. Also see col. 4, lines 51-63 and col. 7, lines 57-67. This amount/range meets Applicants claimed amount of a daily dose of lower than 200 mg as recited in instant claim 16. These amounts are used to advantageously treat hyperlipidemia or hypercholesterolemia (col. 8, lines 18-20).

Deboeck also teaches that the compositions contain from about 5% to 95% by weight of fenofibrate (col. 3, lines 49-58). Moreover, with regards to amounts and/or ranges, the Examiner points out that generally, differences in concentration will not support the patentability of subject matter encompassed by the prior art unless there is evidence indicating such concentration is critical. "[W]here the general conditions of a claim are disclosed in the prior art, it is not inventive to discover the optimum or workable ranges by routine experimentation." In re Aller, 220 F.2d 454, 456, 105 USPQ 233, 235 (CCPA 1955).

The pharmaceutical compositions offer increased bioavailability of the fenofibrate as compared to conventional formulations (col. 3, lines 36-38).

It would have been obvious to one of ordinary skill in the art at the time the invention was made to incorporate a fenofibrate formulation that comprises a daily effective amount of fenofibrate in amounts lower than 200 rag, such as about 100 mg as

taught by Deboeck within the lipid formulations of Krause. One of ordinary skill in the art would be motivated to do so with a reasonable expectation of success because Deboeck explicitly teaches fenofibrate pharmaceutical compositions whereby the daily effective amount of fenofibrate for humans ranges from about 100 mg to 600 mg per day and Deboeck teaches that these amounts are used in order to advantageously and effectively treat hyperlipidemia or hypercholesterolemia. The expected result would be an improved fenofibrate formulation that has increased bioavailability for the beneficial treatment of hyperlipidemic and high cholesterol conditions.

Regarding the claim 16 and 42 limitations of "bioavailability being greater than that of Lipanthyl®200M" this limitation does not impart patentability to the present claims. Example 3 on page 12 of the specification indicates that the enhanced bioavailability occurs as a result of the specific bioavailability parameters (AUC, Cmax, Tmax). However, the instant claims are entirely generic in this regard. The instant claims do not introduce any specific dissolution profiles, rates of release, nor any specific AUC, Cmax, Tmax levels, which would distinguish over the teachings of the prior art. The claims are silent in terms of these specific features. Thus, the limitation does not define over the prior art disclosure. The instant claims are generic in scope as compared to that with the particular examples (i.e., Example 3) of the specification.

Regarding claims 41-45, which recite a fenofibrate tablet wherein the 'bioavailability is assessed by AUC, Cmax or both', it is the position of the Examiner that this limitation is met by the combination teachings of the prior art. The prior art explicitly

teaches fenofibrate formulations having increased bioavailability of fenofibrate as compared to conventional formulations. See for instance, Deboeck col. 3, lines 36-38.

The art further teaches bioavailability parameters (AUC, Cmax, Tmax) and teaches suitable bioavailability levels (see Table 4 of Deboeck at column 8). The manner by which the bioavailability of fenofibrate is assessed does not impart patentability to the claims since the art clearly recognizes fenofibrate formulations that exhibit increased or improved bioavailability. Moreover, a product is being claimed herein and not a method of assessing bioavailability of an active ingredient. It is the patentability of the product that must be established and not the manner by which bioavailability is achieved or assessed. Furthermore, Applicant credits the improved bioavailability of their composition based on their fenofibrate processing techniques. It is noted that the instant claims are drawn to a product and not a process of manufacturing fenofibrate. In any event, the prior art teaches fenofibrate products having increased or improved bioavailability. The art further recognizes using low dosage of fenofibrate (200 mg) to achieve therapeutic effects (i.e., bioavailability).

*

* * * * *

Response to Arguments

Applicants' arguments filed 21 March 2011 have been fully considered and are partially persuasive; as such, the obviousness rejection in view of the Ghebre-Sellassie reference is hereby withdrawn.

Applicants argue that the dosage taught by Krause, "...includes a far larger amount of fenofibrate than the composition of the present invention." See remarks, page 2.

Examiner respectfully submits that while Krause teaches a lower limit fenofibrate of 300 mg per day (as compared with the "lower than 200 mg" being claimed instantly), the secondary reference cited in the rejection, Deboeck, teaches fenofibrate administration of as low as 100 mg per day (see col. 8, lines 18-24). One cannot show nonobviousness by attacking references individually where the rejections are based on combinations of references. See *In re Keller*, 642 F.2d 413, 208 USPQ 871 (CCPA 1981); *In re Merck & Co.,* 800 F.2d 1091, 231 USPQ 375 (Fed. Cir. 1986).

Applicants argue that, "...no combination is made [in the instantly claimed composition] with another pharmaceutically active agent..." See remarks, page 2.

Examiner respectfully submits that the instant claims as currently constructed do not preclude elements other than those recited in the claims since the closed transition phrase "consisting of" is not used.

Applicants argue that, "[t]he sole relationship between the Krause reference and the invention is that the previous reference mentions fenofibrate..." See remarks, page 2.

Examiner respectfully disagrees. Krause, in combination with Deboeck, suggests the instant claims as currently constructed; Kraus, like the instantly claimed composition, teaches an orally administrable composition comprising fenofibrate. The

composition disclosed by Krause may be formulated as an immediate release tablet. See substantive rejections, above.

Applicants argue that the composition taught by Deboeck has a bioabailability comparable to that of LIPANTHYL 200M™, while the composition of the instant application demonstrates higher bioavailability than LIPANTHYL 200M™. See remarks, page 3.

At the outset, examiner respectfully submits that the instant claims do not recite LIPANTHYL 200M™, rather, the generic description claimed is "200mg co-micronized fenofibrate". However, this generic description does not contain the essential components of LIPANTHYL 200M™; for example, the generic description does not specify what is being co-micronized with the fenofibrate; additionally, the generic description does not mention co-micronization with a solid wetting agent, or a capsule filling agent, both of which are essential components of LIPANTHYL 200M™ (see, e.g., Deboeck, col. 1, lines 46-52). As such, any comparison between the instantly claimed composition and the specific formulation of LIPANTHYL 200M™ is not proper, as the claims do not recite a complete generic description of LIPANTHYL 200M™.

Additionally, independent claims 16 and 42 only require that the bioavailability be "greater". The claims do not indicate how much "greater" the bioavailability needs to be; as such, a *de minimus* improvement would read on the instant claims. Deboeck shows such an improvement in Table 4, in the "without food" group, where the AUC for the disclosed composition was 107.0 while that of LIPANTHYL 200M™ was 101.0.

* * * * *

Conclusion

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to HASAN AHMED whose telephone number is (571)272-4792. The examiner can normally be reached on 9am - 5:30pm.

Correspondence

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Robert A. Wax can be reached on (571)272-0623. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/H. A./
Examiner, Art Unit 1615

/Robert A. Wax/
Supervisory Patent Examiner
Art Unit 1615